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10/590,038	11/17/2006	Edward Zbygniew Nowak	061170-0235	5625

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MCDERMOTT WILL & EMERY LLP  
600 13th Street, NW  
Washington, DC 20005-3096

EXAMINER
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PURDY, KYLE A

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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03/30/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/590,038		NOWAK, EDWARD ZBYGNIEW	
	<b>Examiner</b>		<b>Art Unit</b>	
	KYLE PURDY		1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 1/10/2011.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-26, 28, 30-35 and 37-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18-26, 28, 30-35 and 37-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Status of Application

1. The Examiner acknowledges receipt of the arguments and amendments filed on 1/10/2011.
  2. Claims 16, 18-26, 28, 30-35 and 37-39 have been amended. Claims 41-55 have been newly added.
  3. Claims 16, 18-26, 28, 30-35, 37-40 and 41-55 are presented for examination on the merits.
- The following rejections are made.

### *Response to Applicants' Arguments*

4. Applicants arguments filed 1/10/2011 regarding the rejection of claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 made by the Examiner under 35 USC 102(b) over Inaba et al. (US 4552751) have been fully considered but they are not persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 9/10/2010.

5. In regards to the 102(b) rejection, Applicant asserts the following:

A) The claims as amended overcome the rejection of record. More specifically, claim 16 has been amended to require that the active ingredient be dissolved in a polar solvent and subsequently applied to the surface of the non-gelatin polymeric film.

6. In response to A, the claims as amended do not overcome the rejections of record. Applicant has amended the product by process claims such that the process requires applying a pharmaceutically active polar liquid mixture to a surface of an inactive non-gelatin film and then curing the active transport medium to form a homogenous film-active transport medium composition. With respect to the use of a polar liquid carrier for carrying the active agent, this limitation is disclosed by Inaba. Inaba states that "the organic solvent to be used may be....

methanol, ethanol, acetone, methylene chloride.” See column 5, lines 60-65. It’s noted that each of the solvents disclosed by Inaba are polar.

7. Aside from this added limitation, it’s unclear how the process distinguishes the claimed product from the product of the art. Inaba discloses making a multilayered dosage system wherein a drug containing film forming organic solvent is applied to an inactive non-gelatin polymeric film and then subsequently dried and cured to form a homogenous multilayered film. It’s still the Examiners position that following the steps disclosed of Inaba would produce the composition instantly claimed. Applicants arguments/amendments are not persuasive and do not overcome the rejections of record.

8. Applicants arguments filed 1/10/2011 regarding the rejection of claims 25 and 32 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen et al. (US 2003/0183643) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 9/10/2010.

9. In regards to the 103(a) rejection, Applicant asserts the following:

**B)** The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

10. In response to B, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiners response to assertions A.

11. Applicants arguments filed 1/10/2011 regarding the rejection of claims 21, 22 and 37-39 made by the Examiner under 35 USC 103(a) over Inaba in view of Patel et al. (US

2004/0253434) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 9/10/2010.

12. In regards to the 103(a) rejection, Applicant asserts the following:

C) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

13. In response to C, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiner's response to assertions A.

14. Applicant's arguments filed 1/10/2011 regarding the rejection of claim 30 made by the Examiner under 35 USC 103(a) over Inaba in view of Brown et al. (US 6783768) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 9/10/2010.

15. In regards to the 103(a) rejection, Applicant asserts the following:

D) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

16. In response to D, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiner's response to assertions A.

17. Applicant's arguments filed 1/10/2011 regarding the rejection of claims 33 and 34 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen and Lynn et al. (US 7112361) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 9/10/2010.

18. In regards to the 103(a) rejection, Applicant asserts the following:

E) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

19. In response to E, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiner's response to assertions A.

**Maintained Rejections, of Record (claims 16, 18-26, 28, 30-35 and 37-39) and New Rejections, Necessitated by Amendment (claims 41-55)**  
**Claim Rejections - 35 USC § 102**

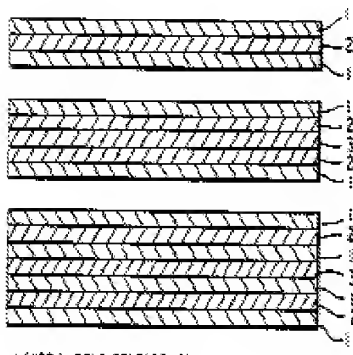
20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. **Claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al. (US 4552751; of record).**

22. Inaba is directed to long-lasting multi-layered film preparations. The structure of the films are disclosed to have the following structures:



(see abstract).

Layer 1 corresponds to a drug release controlling layer and Layers 2 and 3 correspond to drug storing layers. The multilayered dosage forms are gelatin free. The polymers used in the films

include hydroxypropyl methylcellulose and polyvinylpyrrolidone (see column 2, line 15). The method of making such films is as follows: A) make a drug-free film layer liquid formulation; B) cast A to form the film; C) make a drug-containing film layer liquid formulation; D) pour drug film liquid onto film A and let dry; and E) repeat indefinitely until desired dosage form has been prepared (see column 5, lines 10-20 and Example 1; see instant claims 16, 23, 24, 26, 28, 31, 35 and 40). It is noted that Applicants definition of monolith is simply a multi-layered dosage form. It should be pointed out that as one layer is drug free and one layer contains drug, there is necessarily a concentration gradient present in the film (see instant claim 18). Because the references multi-layered film compositions are identical to the instant claims, the final film would inherently have a homogenous structure.

23. The instant claims are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by those steps. So although Inaba may slightly differ in their process of making such films, the final product anticipates the instantly claimed film composition.

24. Furthermore, the claimed product and the product of the art are substantially identical in that they both are structured with inactive non-gelatin polymeric layers with active material dispersed therein. Where the claimed and prior art products are identical or substantially identical in composition, said composition must have the same properties, unless shown otherwise. See MPEP 2112.01. Thus, absent any evidence to the contrary, it would be expected that the product of Inaba would possess muco-adhesive properties.

25. Therefore, Inaba properly anticipates the instantly rejected claims.

**Claim Rejections - 35 USC § 103**

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**27. Claims 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Fagen et al. (US 2003/0183643).**

28. Inaba is relied upon for disclosure described in the rejection of claims 16 under 35 U.S.C. 102(b).

29. Inaba teaches a multilayered film which possess five layers (see Example 5 and claim 11; see instant claim 32). Moreover, Figure 1 illustrates a film form which has 7 layers.

30. Inaba fails to teach the film being packaged to form a dose unit.

31. Fagen cures this deficiency. Fagen is directed to packaging of films such that individual sheets of the film are dispensed one at a time (see [0001]; see instant claim 25). It is taught that the packaging is useful because it protects unused products during repeated opening and closing (see [0005]).

32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Fagen to arrive a product wherein the films are packaged to form a unit dose. One would have been motivated to package the unit doses of the films disclosed by Inaba because it would protect the unused films thereby preventing exposure to moisture and potential environmental degradation of the drug and/or film. Therefore, a packaged unit dose of a drug loaded non-gelatin film is prima facie obvious to one



of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**33. Claims 21, 22 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Patel et al. (US 2004/0253434).**

34. Inaba is relied upon for disclosure described in the rejection of claims 16 and 18-20 under 35 U.S.C. 102(b).

35. Inaba fails teach the film as being coiled or zigzag.

36. Patel cures these deficiencies. Patel is directed to water-soluble films systems with actives entrapped therein (see abstract). It is disclosed that the films can be in a rolled (i.e. coiled) or fanfold form (i.e. zigzag shape) (see [0197] and page 3). It is taught that such a shape is useful to selectively entrap interacting/non-interacting materials and their combinations (see abstract).

37. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Patel with a reasonable expectation for success in arriving at a film composition wherein the film is in a coiled or zigzag shape. Inaba is discussed above. Briefly, Inaba discloses a non-gelatin film that has an drug solution applied to it and subsequently cured. Inaba fails to teach the shape of the film. Patel cures these deficiencies. Patel teaches that their water-soluble films are capable of being shaped into coiled or zigzag forms. One would have been motivated to shape the films to such forms because it would aid in entrapping interacting and non-interacting materials. Moreover, such shapes would provide a more compact and convenient means for retaining the film material. Therefore, a non-

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gelatin film in the shape of a coil or zigzag is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**38. Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Brown et al. (US 6783768).**

39. Inaba is relied upon for disclosure described in the rejection of claim 16 under 35 U.S.C. 102(b).

40. Inaba fails to teach the film as being employed to coat tablets or capsules.

41. Brown cures these deficiencies. Brown is directed to coating tablet cores with pharmaceutically active films (see abstract). The coating may be applied electrostatically or by inkjet (see column 16, lines 20-25). It is taught that such coatings can help to reduce the size of the dosage form as well as to minimize variation in the dose delivered (see column 1- column 2).

42. Therefore, it would have be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Brown with a reasonable expectation for success in arriving at a film capable of coating a tablet. One would have been motivated to coat a tablet or capsule with the film of Inaba because it would reduce the size of the dosage form by minimizing the amount of inert ingredients as well as help to reduce the variation in the dosage delivered. Therefore, a tablet or capsule coated with a drug containing non-gelatin film is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**43. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Fagen et al. (US 2003/0183643) and Lynn et al. (US 7112361).**

44. Inaba and Fagen is relied upon for disclosure described in the rejection of claim 25 under 35 U.S.C. 102(b).

45. Inaba and Fagen fail to teach the number of layers on the monolith as being greater than 10.

46. Lynn cures this deficiency. Lynn is directed to decomposable films containing polyelectrolytes. It is taught that the films can contain pharmaceutical actives. Lynn teaches a film which has 10 bilayers, wherein each bilayer comprises of poly(b-amino ester) and poly(sodium 4-styrenesulfonate). Thus, the final film has 20 layers (see instant claims 33 and 34). It is taught that the number of layers controls the release rate of the entrapped substances, i.e. a drug (see column 11, line 25).

47. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Inaba, Fagen and Lynn with a reasonable expectation for success in arriving at a multilayered film composition which comprises more than 10 layers. Inaba suggests such a composition by teaching that multi-layered dosage form is to have at least one drug storing layer and at least two drug releasing layers. Furthermore, Inaba teaches a composition which has 7 layers. Based on the teaching of Inaba one would have been motivated to make a film composition having multiple layers. If such a result was a film product that had 10 layers, then that would be a product of ordinary skill and common sense because Inaba indirectly suggests making such a composition. Regardless, Inaba fail to explicitly teach a

multilayered film having at least 10 layers. Lynn cures this deficiency. Lynn teaches a multilayer film formulation that can have up to 20 layers. One would have been motivated to modify the teaching of Inaba because in doing so would result in adjusting the release rate of the drugs from the dosage form. Therefore, a non-gelatin film possessing more than 10 layers is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

### ***Conclusion***

48. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

49. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

50. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

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51. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

52. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/  
Examiner, Art Unit 1611  
March 22, 2011

/SHARMILA G. LANDAU/  
Supervisory Patent Examiner, Art Unit 1611